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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/866,569

05/25/2001

Anthony E. Bolton

355908-3100

4479

38706

7590

12/05/2006

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/866,569	Applicant(s) BOLTON ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/8/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: BOLTON ET AL

1. The amendment filed 9/20/2006 is acknowledged and entered into the record. Accordingly, claims 1-15, are canceled without prejudice or disclaimer.
2. Claims 16-29 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed on 11/8/2006 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 16-29 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. The examiner would like to apologize for the inadvertent typographical error in the listing of rejected claims. It is also acknowledged that the applicant appears to have argued the rejection based on claims 16-29 in the response filed 9/20/2006. Applicant argues that the claimed invention is fully enabled and supports this contention by referring to the Declaration filed by Dr. Mandel (herein "Mandel Declaration"). Specifically, applicant contends the Mandel Declaration provides support for the opinion that a decrease in pro-inflammatory cytokines or an increase in anti-inflammatory cytokines would correlate with treatment protocols for congestive heart failure (CHF). The Declaration further asserts that one of

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skill in the art would be capable of making a correlation between a model for contact hypersensitivity (CHS) and CHF. This assertion is based on for three basic principles well known in the art at the time of filing. First, contact hypersensitivity (CHS) is a Th-1 mediated disease which is decreased by the addition of anti-inflammatory cytokines. Second, inflammatory cytokines play a role in the pathology of CHF. And third, immunoglobulin-based treatments has been shown to increase anti-inflammatory cytokines. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). Moreover, affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of a pending application are usually not considered. *In re Oppenauer*, 143 F.2d 974, 62 USPQ 297 (CCPA 1944). In this case, the declaration by Dr. Mandel fails to show a clear relationship between CHS and CHF. The etiology of CHS and CHF appear to be completely different and the declaration fails to show that the outcomes for CHS would be indicative for CHF. In addition, the declaration fails to show that the evidence garnered from the CHS model would be predictive of the the administration of apoptotic bodies in CHF subjects. Finally, the declaration is not commensurate in scope to the claimed invention. The claims are drawn to the use of apoptotic bodies in CHF subjects, while the declaration show the administration of anti-inflammatory cytokines. Thus, the Declaration under 37 CFR 1.132 filed 9/20/2006 is

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insufficient to overcome the rejection of claims 16-29 based upon the insufficiency of disclosure under 35 USC 112, 1st paragraph as set forth in the last Office action because: the showing is not commensurate in scope to the claims of the instant invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
November 29, 2006



CHRISTOPHER H. YAEN
PRIMARY EXAMINER